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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,227	11/19/2003	David Karl Stroup		9050

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EXAMINER
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COMPTON, ERIC B

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/718,227

Applicant(s)

STROUP, DAVID KARL

Examiner

Eric B. Compton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/19/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 11, 12-18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA) in view of U.S. Pat. 5,979,637 to Iwamoto et al ("Iwamoto").

AAPA, as found on page 1 of the Specification, discloses: "Assembly or manufacturing systems and methods have been devised in the past for producing diagnostic medical test kits (e.g., at-home pregnancy test kit). However, the inventor is not aware of a diagnostic medical test kit assembly system and method that is automatic, high-throughput, in-line, and flexible in nature to allow for families of related diagnostic medial test kits of different products to be assembled with the same system with minimum manual changeover time." See *also* U.S. Pats, 6,352,862; 5,658,801; 5,656,503; and 4,943,522 (disclosing various diagnostic medial test kits).

Iwamoto discloses an automatic assembly system for assembling an article, which "is flexible in accordance with a change in the production line as a change of the number of steps on the same production line." Col. 1, lines 8-10. Furthermore, the apparatus "can easily be adapted to a revised or new production line having a plurality of steps." Col. 1, lines 44-46. The apparatus comprises: an assembly line (1) having a

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start end, a return end, a conveyor running in a direction; a return line (78) parallel to the assembly line and having a start end, a return end, and a conveyor running in a direction opposite of that of the conveyor of the assembly line; a plurality of pallets (13) carrying components (53) of the article; a plurality of work stations (70-75) disposed along the assembly line to perform assembly steps on the components of the medical test kit; a start end pallet transfer mechanism (69) disposed at the start end of the assembly line and the return line to transfer the pallets from the return line to the assembly line; and a finish end pallet transfer mechanism (76) disposed at the finish end of the assembly line and the return line to transfer the pallets from the assembly line to the return line. The method of assembling the article is inherently provided for as well. See Col. 3, line 48 - Col 5, line 24. Although the reference discloses a preferred embodiment for forming a camera, the reference does notes the assembling line could be configured to form other articles. See Col. 5, lines 26-30.

Regarding claims 1 and 12, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the medical diagnostic medial test kit of AAPA, using an automatic, high-throughput, in-line, and flexible apparatus (and associated method) as claimed, in light of the teachings of Iwamoto, in order to "provide a pallet conveyor which can easily be adapted to a revised or new production line having a plurality of steps." Col. 1, lines 44-46.

Regarding claim 2, the assembly steps of Iwamoto are automatically performed. See *generally* Fig. 2.

Regarding claims 3 and 13, Iwamoto discloses that production lines for different

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articles are envisioned on the same conveyor. See e.g., Col. 1, lines 31-40 (discussing drawbacks of prior art eliminated by invention). Furthermore, the adding or eliminating of steps clearly suggests that workstations are added or removed as well. Figure 3 shows a pallet having registration means (13a, 13b) for engaging the base of the article. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to have provided pallets suitable for different products (or at least having different registration means) in light of the teachings of Iwamoto, in order to form articles having different sizes or dimensions. See *also* U.S. Pat. 5,497,708.

Regarding claims 4 and 14, Iwamoto disclose one assembly operation occurs per machine cycle.

Regarding claims 5 and 15, Iwamoto does not disclose the duration of one cycle. Applicant claims 3,600 cycles per hour (i.e., 1 per minute). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have performed 3,600 cycles per hour (i.e., 1 per minute) or more, in light of the teachings of Iwamoto, in order to increase efficiency.

Regarding claims 6 and 16, Iwamoto relies on a servo-driven motor (23) to advance an indexing conveyor (3, 5, 7) on the assembly line.

Regarding claims 7 and 17, Iwamoto relies on a conveyor on the assembly line having an upper surface with a plurality of cleats (18), which advance the pallets. However, the reference does not disclose recesses on the pallet to engage the cleats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided recesses in the pallets, which engage with the cleats, in

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light of the teachings of Iwamoto, in order to provide even greater registration between the pallet and conveyor.

Regarding claims 8 and 18, Iwamoto does not disclose the type of return line conveyor (78). However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a variable-speed linear return conveyor, in light of teachings Iwamoto, such that dwell time of the return conveyor can easily be synchronized with the dwell time of the assembly conveyor.

Regarding claims 11 and 21, Iwamoto discloses that only empty pallets are returned via the return conveyor (78). However, there is not disclosure of providing a sensor to verify this action taken. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the apparatus (and associated method) with a photo-optic sensor to verify the pallets are returned empty, in light of the teachings of Iwamoto, to prevent the apparatus from jamming due to placing a new base on an un-empty pallet. See U.S. 5,427,252, Col. 8, lines 20-28 (disclosing using photo sensors for verifying the presence/conditions of pallets to avoid jams).

3. Claims 9-10 and 19-20 rejected under 35 U.S.C. 103(a) as being unpatentable over AAPA/Iwamoto as applied to claims 1 and 12 above, respectively, and further in view of U.S. Pat. 6,071,112 to Calvin et al ("Calvin").

AAPA & Iwamoto disclose the invention cited above. However, the references do not disclose the particular steps for assembling the diagnostic medical test kit as claimed especially including an inspection step whereby defective parts are ejected.

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"Stick" type diagnostic medical test kits, like that discussed and claimed by Applicant, are generally known in the art, having a base, a test strip, a wick, a cover, and a cap. See e.g. U.S. Pat. 6,352,862 (showing a base (111), a test strip (114, 116), a wick (113), a cover (110), and a cap (103)). Inherently in an automated production line system the steps of assembling the various parts are provided for, e.g., a base loading station, test strip insertion station, wick loading station, cover loading station, and cap loading station. Official Notice is taken that various pneumatic assembling operations, such as presses are readily available in the production line assembly arts.

Calvin disclose disclosing an optical inspection system for an automated assembly line for producing contact lenses packages for verifying the presence of a foil cover and rejecting those articles which fail inspection. See Col. 25, lines 44-61.

Regarding claims 9-10 and 19-20, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the apparatus (and associated method) of AAPA/Iwamoto with an inspection station whereby defective parts are ejected, in light of the teachings of Calvin to insure/verify proper assembly and discriminate against defective articles.

### ***Prior Art References***

The prior art references listed on the enclosed PTO-892, but not used in a rejection of the claims, are cited for their teachings of assembling articles.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric B. Compton whose telephone number is (571) 272-4527. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter D. Vo can be reached on (571) 272-4690. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric B. Compton  
Primary Examiner  
Art Unit 3726

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